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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/155,590	09/30/98	SCHLOM	J 2026-4230US1

HM22/1011

WILLIAM S FEILER
MORGAN & FINNEGAN
345 PARK AVENUE
NEW YORK NY 10154

EXAMINER

EWOLDT, G

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED: 10/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/155,590Applicant(s)
Schlom et al.Examiner
Gerald EwoldtGroup Art Unit
1644☒ Responsive to communication(s) filed on Jul 24, 2000☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 10-25, 27, and 32-34 is/are pending in the application.Of the above, claim(s) 16-24 is/are withdrawn from consideration.☐ Claim(s) _____ is/are allowed.☒ Claim(s) 10-15, 25, 27, and 32-34 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election with traverse of Group I, Claims 1-37, in Paper No. 13, is acknowledged. Applicant's further election of SEQ ID NO:14 as the specific mutant *ras* peptide, tetanus toxoid as the specific carrier; IL-2 as the specific biological response modifier; and RIBI Detox™ as the specific adjuvant is acknowledged. The traversal is on the grounds that all Groups relate to mutant *ras* peptides and should thus remain together and that carrier molecules, biological response modifiers, adjuvants, and liposomes are well known in the art.

These argument are not found persuasive for the following reasons. While the searches of the related inventions may overlap, the fields of search for different products and methods of using said products are significantly different and not coextensive. Further, the mechanisms by which different carrier molecules, biological response modifiers, adjuvants, and liposomes function, and the efficacies of said carrier molecules, biological response modifiers, adjuvants, and liposomes are significantly different, thus the searches are again not coextensive.

2. A telephone call was made to Ms. Kathryn Brown on 9/27/00 to indicate that the sequence election was considered nonresponsive. At that time Ms. Brown elected YLVVGADGV as the specific sequence to be examined.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 16-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 10-15, 25, 27, and 32-34 are being acted upon.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In claim 10, the recitation of "elicits peptide-specific human CD8⁺ cytotoxic T lymphocytes" renders the claim ambiguous and indefinite. It is unclear just what the phrase means. "Eliciting" a lymphocyte is not a term that is well known in the art.

B) In claim 11, the recitation of "an amino acid sequence of about 13 amino acids" renders the claim ambiguous and indefinite. It is unclear just what length sequence is being claimed.

C) In claim 12 the recitation of "an amino acid sequence of about 10 amino acids" renders the claim ambiguous and indefinite. It is unclear just what length sequence is being claimed.

6. Claim 34 contains the trademark/trade name RIBI Detox™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a pharmaceutical composition and, accordingly, the identification/description is indefinite.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 10-15, 27, and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Van Elsas et al. (1995) or Gjertsen et al. (1996) in view of Ruppert et al. or U.S. Patent No. 5,861,372 (1999).

Van Elsas et al. teaches a mutant ras peptide of about 10 or 13 amino acids in a pharmaceutically acceptable carrier comprising the sequence KLVVVGADGV (see particularly page 391, Table I), that binds human MHC HLA-A and thus would be inherently capable of eliciting CD8⁺ lymphocytes. Note that "eliciting" a

lymphocyte is an indefinite recitation, however, for examination purposes the term is considered to mean eliciting a CD8⁺ response.

Gjertsen et al. teaches a mutant *ras* peptide of about 10 or 13 amino acids comprising the sequence KLVVVGADGVGKSALTI (see particularly page 451, Table I and Table III), that binds MHC HLA-A and elicits CD8⁺ lymphocytes. Note that "eliciting" a lymphocyte is an indefinite recitation, however, for examination purposes the term is considered to mean eliciting a CD8⁺ response.

Van Elsa et al. and Gjertsen et al. differ from the claimed invention in that the peptides taught by the references differ from the claimed peptide species in that the reference peptides begin with an N-terminus K while on the claimed peptide the mutant *ras* N-terminus K has been replaced with a Y.

Ruppert et al. teaches that the addition or replacement of an N-terminus amino acid residue with a Y improves binding of a peptide to HLA-A2 (see particularly page 932, Figure 3).

The '372 patent teaches that Y can be added to peptide fragments to facilitate the addition of detectable labels to said fragments (see particularly column 22, lines 25-28).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace an N-terminus K, on the mutant *ras* peptide taught by Van Elsa et al. or Gjertsen et al., with an N-terminus Y, as taught by Ruppert et al. or the '372 patent. One of ordinary skill in the art would have been motivated to make said change to facilitate either better HLA-A2 binding, as taught by Ruppert et al., or to facilitate labeling, as taught by the '372 patent.

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Elsas et al. (1995) or Gjertsen et al. (1996) in view of Ruppert et al. or U.S. Patent No. 5,861,372 (1999) as applied to claims 10-15, 27, and 32 above, and further in view of U.S. Patent No. 6,039,948 (2000).

Van Elsas et al. (1995), Gjertsen et al. (1996), Ruppert et al. and U.S. Patent No. 5,861,372 (1999) have been discussed *supra*.

The reference teachings differ from the claimed invention in that they do not teach a mutant *ras* peptide conjugate comprising said peptide and tetanus toxoid.

The '948 patent teaches a tetanus toxoid-peptide conjugate. Said conjugate was used as an adjuvant to elicit an improved immune response when compared to the peptide alone (see particularly, Figures 7 and 8 and column 8, lines 39-47).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a mutant *ras* peptide-tetanus toxoid conjugate, as taught by Van Elsas et al. (1995), Gjertsen et al. (1996), Ruppert et al., U.S. Patent No. 5,861,372 (1999), and U.S. Patent No. 6,039,948 (2000). One of ordinary skill in the art would have been motivated to make said conjugate as an immunogen to elicit an improved response when compared to a peptide alone, as taught by the '948 patent.

10. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Elsas et al. (1995) or Gjertsen et al. (1996) in view of Ruppert et al. or U.S. Patent No. 5,861,372 (1999) as applied to claims 10-15, 27, and 32 above, and further in view of U.S. Patent No. 5,800,810 (1998).

Van Elsas et al. (1995), Gjertsen et al. (1996), Ruppert et al. and U.S. Patent No. 5,861,372 (1999) have been discussed *supra*.

The reference teachings differ from the claimed invention in that they do not teach a mutant *ras* peptide composition further comprising said peptide and interleukin 2 (IL2).

The '810 patent teaches a pharmaceutical composition comprising an immunogen and IL2. IL2 was used as an adjuvant to elicit an enhanced immune response when compared to the immunogen alone (see particularly, column 3, lines 5-9).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a mutant *ras* IL2 pharmaceutical composition, as taught by Van Elsas et al. (1995), Gjertsen et al. (1996), Ruppert et al., U.S. Patent No. 5,861,372 (1999), and U.S. Patent No. 5,800,810 (1998). One of ordinary skill in the art would have been motivated to make said composition to elicit an enhanced immune response when compared to an immunogen alone, as taught by the '810 patent.

11. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Elsas et al. (1995) or Gjertsen et al. (1996) in view of Ruppert et al. or U.S. Patent No. 5,861,372 (1999) as applied to claims 10-15, 27, and 32-33 above, and further in view of U.S. Patent No. 6,001,349 (1999).

Van Elsas et al. (1995), Gjertsen et al. (1996), Ruppert et al., U.S. Patent No. 5,861,372 (1999), and U.S. Patent No. 5,800,810 (1998) have been discussed supra.

The reference teachings differ from the claimed invention in that they do not teach a mutant *ras* peptide composition further comprising said peptide, (IL2), and RIBI Detox™.

The '349 patent teaches a pharmaceutical composition comprising an immunogen and the adjuvant RIBI Detox™. RIBI Detox™ was used as an adjuvant to elicit an enhanced immune response when compared to the immunogen-IL2 composition alone (see particularly, column 6, line 1).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a mutant *ras* peptide, IL2, RIBI Detox™, pharmaceutical composition, as taught by Van Elsas et al. (1995), Gjertsen et al. (1996), Ruppert et al., U.S. Patent No. 5,861,372 (1999), U.S. Patent No. 5,800,810 (1998), and U.S. Patent No. 6,001,349 (1999). One of ordinary skill in the art would have been motivated to make said composition to elicit an enhanced immune response when compared to an immunogen alone, as taught by the '349 patent.

12. No claim is allowed.


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Art Unit 1644

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
September 7, 2000


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600